March 6, 2006

Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd.
Baltimore, MD 21244
PartDformularies@cms.hhs.gov

Re: 2007 Draft Guidelines for Formulary Guidance

Thank you for the opportunity to comment on the notice on how CMS will review Medicare prescription drug benefit plans for their ability to provide adequate access to clinically appropriate medications to beneficiaries through formulary guidance.

The American Academy of HIV Medicine is an independent organization of HIV Specialists and others dedicated to promoting excellence in HIV/AIDS care. Through advocacy and education, the Academy is committed to supporting health care providers in HIV medicine and to ensuring better care for those living with AIDS and HIV disease. AAHIVM members provide direct care to more than 315,000 HIV patients. This is more than two thirds of the patients in active treatment for HIV disease.

AAHIVM appreciates that CMS has previously recognized the delicate nature of HIV clinical care and the need for every drug plan to include all antiretrovirals on their formularies. As you are aware, people with HIV/AIDS who qualify for Medicare usually do so through a designation of disability, for which they must then wait an additional two years for Medicare eligibility. These patients have often exhausted first- and second-line antiretroviral treatment regimens and are in severe need of all available options, both those which are currently FDA-approved and those which will be.

The draft guidance suggests that any drug approved after April 16th, 2006 must then go through the Pharmacy and Therapeutics (P&T) Committee process before they would be made available on drug plan formularies. The P&T process allows for a 90-day review period and 180-day coverage determination period, which is an unacceptable barrier to those who have exhausted all other treatment options. We urge you to again recognize the time-sensitive need for all approved antiretrovirals to be made available for those Medicare beneficiaries with HIV/AIDS and require drug plans to immediately cover all antiretrovirals as they are approved by the FDA.

We are also concerned that the formulary guidance does not explicitly exclude antiretrovirals or the other five protected classes from the “specialty tier” status, and further, that antiretroviral drugs because of their cost could be designated as specialty drugs by drug plans. In 2006, we have heard from Medicare beneficiaries that their plan had inappropriately designated antiretrovirals as “specialty” drugs that could only be filled via mail order. While CMS corrected the problems when reported, we are very concerned that other plans may have placed similar
restrictions on the antiretroviral class that have not been reported because beneficiaries are not aware that this is not allowed. We recommend that CMS more clearly define the drug classes that are appropriate for the specialty tier status and exclude antiretrovirals from this designation.

Further, mail-order pharmacies themselves can pose some practical barriers of their own. While mail-order pharmacies may be more cost-effective for plans, lack of choice means that many confused patients may run out of medication before they can possibly enroll. We should also note that requiring mail-order pharmacy use is a barrier to those without a permanent address.

Finally, we remain very concerned that plans that place antiretrovirals in high cost-sharing tiers effectively make those drugs unavailable to beneficiaries with HIV/AIDS who may be enrolled in those plans. Cost-sharing can be quite prohibitive, depending on the plan. AIDS Drug Assistance Programs (ADAPs) are able to help in some, though certainly not all instances.

Barriers to therapy can be quite dangerous. Adherence to antiretroviral therapy is critical since full suppression of viral replication requires near perfect adherence. Poor adherence can result in the development of drug resistant strains of the virus, which may then be passed on to another individual, compromising effective control of the epidemic and presenting a serious threat to public health. Since near perfect adherence to antiretroviral medications is required for successful treatment of HIV infection, treatable medical conditions which are barriers to adherence must be addressed, including prohibitive cost-sharing.

As CMS has already recognized by designating anti-HIV drugs as one of six protected classes, antiretroviral therapies are not interchangeable with one another. Beneficiaries are not able to simply switch to another lower-cost medication when the combined co-payments of their current therapy are prohibitively high.

Therefore, we recommend that you consider policy in the 2007 formulary guidance documents by which all antiretrovirals must be placed in the lowest cost-sharing tier for each individual plan.

In addition, we strongly encourage you to increase your efforts to enforce compliance with the formulary guidelines—to ensure that best practices are being followed and to ensure that no class of beneficiaries, including people with HIV/AIDS are priced out of any CMS-approved prescription drug plan due to excessively high cost-sharing for their life-saving therapies.
We look forward to working with you more closely to improve the ongoing implementation of this benefit. We make our membership available to you through our Director of Public Policy, Greg Smiley. Mr. Smiley may be reached at (202) 659-0699 or through e-mail (greg@aaihvm.org).

Thank you for your consideration.

Sincerely,

Howard A. Grossman, M.D.
Executive Director
American Academy of HIV Medicine